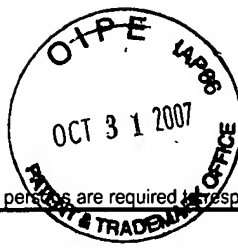


Doc Code: AP.PRE.REQ



PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

2676-608545

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number

10/666,778

Filed

9/18/2003

First Named Inventor

Alain Groossens

Art Unit

1638

Examiner

R. Kallis, Ph.D.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 55,896

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____


Signature

Daniel J. Morath
Typed or printed name

(801) 994-8748
Telephone number

10/30/2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Pursuant to the Pre-Appeal Brief Conference Pilot Program, as published in the Official Gazette on July 12, 20025, applicants submit the following reasons for review:

ARGUMENT

Claims 1-13 and 15-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being obvious over Theodoulou (Biochem. Biophys. Acta 1465 79-103) (hereinafter “Theodoulou”) in view of Dudler *et al.* (J. Biol. Chem. 267:9 5582-5588) (hereinafter “Dudler”), and in further view of Sidler *et al.* (The Plant Cell, Oct. 1998; Vol. 10, 1623-1636) (hereinafter “Sidler”) (hereinafter collectively “the references”). Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants note that the PTO is subject to the Administrative Procedures Act and thus their conclusions must be supported by substantial evidence. *See, e.g., Dickinson v. Zurko* 527 U.S. 150 (1999); and *In re Sang-Su Lee*, 277 F.3d 1338 (C.A.Fed.,2002).

As applied to the determination of patentability *vel non* when the issue is obviousness, “it is fundamental that rejections under 35 U.S.C. § 103 must be based on evidence comprehended by the language of that section.” *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed.Cir.1983). The essential factual evidence on the issue of obviousness is set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. *In re Sang Su Lee* at 1342 -1343.

Applicants submit that determinations of a reasonable expectation of success and unexpected results are part of the factual inquiries underlying a legal determination of obviousness and “must be based on objective evidence of record.” *Id.* at 1343; *see also, In re Kotzab* (217 F.3d 1365, 1369 (Fed, Cir. 2000)) and *In re Merck & Co., Inc.* (800 F.2d 1091, 1097 (Fed. Cir. 1986)). Applicants note that the evidence of record in the present application consists of the materials supplied in applicants IDS, the Declaration of Dr. Alain Goossens, as well as the references which are cited by the Examiner as basis for the obviousness rejection of claims (as noted *supra*).

Applicants submit that the references, in and of themselves, make no determination as to whether the claims of the present application embody unexpected results or as to whether there was a reasonable expectation of success in practicing the methods claimed. Any interpretation, argument, or finding by the Examiner as to what those references may or may not teach in relation to the claims at issue is based on the subjective belief of the Examiner and thus cannot

be considered evidence of record.

In contrast, the sworn Declaration of Dr. Alain Goossens, evidence of record which must be considered by the Patent and Trademark Office (In re Sullivan, 498 F.3d 1345, 1351 (Fed. Cir. 2007)) makes clear statements regarding the unexpected nature of the results embodied in the pending claims and the lack of any reasonable expectation of success for one of ordinary skill in the art to arrive at the claimed methods. Declaration of Dr. Alain Goossens at points 5 and 6. In addition, and as noted in the Declaration of Alain Goossens, these statements are based upon experimental data that is also, by virtue of being included in the Declaration, evidence of record. Applicants note that the Examiner has provided no evidence of record to rebut the Declaration of Dr. Alain Goossens.

Thus, when viewed as a whole (as required under M.P.E.P. § 2141.02(VI)), the evidence of record, through clear and unambiguous statements therein, weighs for a finding that the pending claims embody unexpected results and that there was no reasonable expectation of success in practicing the claimed methods. Applicants note that the evidence in support of such a finding has not been challenged by other evidence, but only by Examiner argument interpreting the evidence of record.

In view of the foregoing, applicants respectfully submit that there is a clear legal and factual deficiency in the rejection of the present claims as the evidence of record, which must form the basis of any agency decision, provides a conclusion of non-obviousness through a direct finding of unexpected results and no reasonable expectation of success. Furthermore, applicants submit that there is no other evidence of record that makes direct statements contravening the explicit statements of the evidence regarding unexpected results and no reasonable expectation of success. Consequently, applicants respectfully request that the rejections be withdrawn and the claims reconsidered.

In addition, applicants note that to establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. Applicants respectfully submit that the references do not teach or suggest at least “wherein said ABC-transporter functions to transport at least one secondary metabolite in plant cells” or “selecting transformed plant cells having an induced or enhanced production or secretion of at

least one secondary metabolite” as recited by claim 1. Although not argued herein pursuant to space limitations, applicants note that similar elements appear in claims 7, 10, 12, and 16, and arguments similar to those now presented in relation to claim 1 can be easily generated and extended to those claims.

The Examiner, at page 2 of the Advisory action, asserts that the references direct one of skill in the art “to characterize the ABC transporters for the type of secondary metabolite transported and vacuolar transport using a transgenic plant approach . . . and thus one of ordinary skill in the art is directed to select for induced or enhanced activity.” Applicants note that selecting for induced or enhanced activity of an ABC transporter does not teach that the ABC transporter at issue transports a secondary metabolite or selecting cells having induced or enhanced production or secretion of at least one secondary metabolite as recited by claim 1. Applicants further note that not all ABC transporters function to transport secondary metabolites and that selection based induced or enhanced transport into an intracellular space (the vacuolar space), bears no reasonable connection to selection based on enhanced or induced production or secretion (which by definition is directed to an extracellular space) of a secondary metabolite.

The Examiner notes that the references teach that increased levels of AtPGP1 (an ABC transporter) resulted in increased hypocotyl elongation. The Examiner then postulates (in hindsight) that this is most likely the result of increased auxin transport, and auxin is a secondary metabolite, thus showing induced or enhanced production or secretion of a secondary metabolite. Applicants note that such a conclusion by the Examiner is based on subjective belief and unknown authority as the Examiner has provided no evidence of record in support of the proposition auxin is a secondary metabolite. Applicants further note that the evidence of record purported to show that AtPGP1 transports a secondary metabolite or that increased levels of an AtPGP1 leads to increased hypocotyl elongation through increased auxin transport never even mentions the words “auxin” or “secondary metabolite” in the text of the article (*see*, Dudler). Applicants note that factual questions material to patentability cannot be resolved on subjective belief and unknown authority. In re Sang Su Lee at 1344.

In addition, the evidence of record suggests that AtPGP1 might be involved in the export of signal compound, possibly a peptide hormone. Theodoulou at page 86, first full paragraph. Applicants note that no suggestion in the references that the signal compound, which might be a

peptide hormone, is a secondary metabolite. Thus, applicants submit that the evidence of record does not support the statements of the Examiner that auxin is a secondary metabolite and, further that, even if auxin is a secondary metabolite, the evidence does not show that auxin production or secretion is induced or enhanced as required by claim 1. Further, the evidence does indicate that the ABC transporter at issue (AtPGP1) actually transports a secondary metabolite. At most, its function is disclosed as unknown and postulated to be a peptide hormone which may or may not be a secondary metabolite.

Further, the Examiner relies on the teachings of Rea et al. (WO 98/21938) for the assertion that Rea teaches a method for increasing pigment (a secondary metabolite) transport into plant vacuoles by transformation with GS-X (an ABC transporter). As a preliminary matter, applicants respectfully submit that it is improper for the Examiner, in positing an obviousness rejection, to rely on the teachings of art which do not form the stated basis of the obviousness rejection. If the Examiner wishes to continue to rely on the teachings of Rea in a formulation of obviousness, applicants respectfully request the Examiner withdraw the present rejection and present a new rejection explicitly setting forth Rea as a basis of that rejection.

In relation to the asserted teachings of Rea, applicants note that increasing pigment transport into vacuoles does not teach selecting cells having induced or enhanced production or secretion of at least one secondary metabolite as recited by claim 1. Applicants submit that increased transport into an intracellular compartment does not teach cells having increased production or secretion. Moreover, Rea does not teach the selection of cells on this basis as required by claim 1.

Last, the examiner notes that “the test is what the combined references would have suggested to those of ordinary skill in the art.” Advisory Action at page 2. However, the Examiner has not pointed out where the combined references suggest the claim limitations at issue and has provided no evidence noting what those references would suggest.

In view of at least the foregoing, applicants respectfully request withdrawal of the rejections of claims 1-13 and 15-19 under 35 U.S.C. § 103(a) and reconsideration of same.

Serial No. 10/666,778

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dan Morath', with a long horizontal flourish extending to the right.

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Date: October 30, 2007